Translation

PATENT COOPERATION TREATY

PCT/FR2003/003293

529319

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/FR2003/003293	International filing date (*day/month/year*) 04 novembre 2003 (04.11.2003)	Priority date (*day/month/year*) 05 novembre 2002 (05.11.2002)
International Patent Classification (IPC) or national classification and IPC C07K 14/315		
Applicant UNIVERSITE DE LA MEDITERRANEE (AIX-MARSEILLE II)		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
16 avril 2004 (16.04.2004)	01 March 2005 (01.03.2005)
Name and mailing address of the IPEA/EP Facsimile No.	Authorized officer Telephone No.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/FR2003/003293

I. Basis of the report

1. With regard to the elements of the international application:*

☐ the international application as originally filed

☒ the description:

pages 1-49, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☒ the claims:

pages 1-19, as originally filed
pages _____, as amended (together with any statement under Article 19
pages _____, filed with the demand
pages _____, filed with the letter of _____

☒ the drawings:

pages 1-1, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the sequence listing part of the description:

pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☒ furnished subsequently to this Authority in written form.

☒ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☒ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____
☐ the claims, Nos. _____
☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/FR 03/03293

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	6-13, 15, 16, 18	YES
	Claims	1-5, 14, 17, 19	NO
Inventive step (IS)	Claims	6-13, 15, 16, 18	YES
	Claims	1-5, 14, 17, 19	NO
Industrial applicability (IA)	Claims	1-13, 15-19	YES
	Claims	14	NO

2. Citations and explanations

1. This report makes reference to the following documents:

D1: EMBL Database
Accession Number AE00141199

D2: EMBL Database
Accession Number AE006480

D3: EMBL Database
Accession Number AE009961

D4: EMBL Database
Accession Number AE008542

D5: EMBL Database
Accession Number AE015022

D6: US-B-6420135

D7: WO 02/077021

2. Document D8 was not cited in the international search report. A copy of that document is attached.

D8: WPI Database
Derwent publications AN 2004-101891
& FR-A-2,824,074 (31 October 2002)

3. D1 describes the *rpoB* gene sequence of the

Streptococcus agalactiae bacteria (4582-8157 nucleotides). That sequence shows 99.4% identity with the nucleotide sequences of SEQ ID No. 22 and 23 in the present application. Regardless of its high identity rate with SEQ ID No. 22, the sequence described in D1 shows differences from the sequence of SEQ ID No. 22 in the present application at positions 1-4, 7, 704, 706 and 730 of SEQ ID No. 22. For this reason, the sequence described in D1 is not excluded from the scope of claim 1.

The scope of claim 3 includes sequences showing at least 98.7% homology with the sequences of SEQ ID No. 8-35. The sequence described in D1 shows more than 98.7% identity with the sequences of SEQ ID No. 22 and 23. Consequently, the subject matter of claims 1 and 3 is not novel over D1 (PCT Article 33(2)).

4. D8 describes, in particular, the *rpoB* gene sequence of the *Streptococcus agalactiae* bacteria. The sequences described in D8 show, in particular, more than 99% identity with the nucleotide sequence of SEQ ID No. 22 in the present application. D8 also mentions diagnostic (and hence detection) methods for bacteria, said methods being based on the use of these sequences, as well as kits used to implement these methods (abstract; SEQ ID No. 127 and 6499).

Consequently, the subject matter of claims 14, 17 and 19 is not novel over D8 (PCT Article 33(2)).

5. Claims 1-3 and 14 refer to sequences showing "at least 98.7% homology". However, since the present application does not contain a definition of the

term "homology" that would diverge from the generally recognised definition, the latter should be evaluated as having the meaning a person skilled in the art would normally give it. The term "homology" means that these sequences have a common origin. Claims 1-3 and 14 thus refer to sequences having a common origin. The *rpoB* genes described in documents D1-D8 have a common origin with the *rpoB* genes of SEQ ID No. 1-3, 5 and 8-35 described in the present application. Consequently, the subject matter of claims 1-5, 14, 17 and 19 is not novel over D1, D2, D3, D4, D5, D6, D7 or D8 (PCT Article 33(2)).

6. Should the applicant succeed in overcoming the above objections on the grounds of lack of novelty, the Examining Authority is of the opinion that the subject matter of claims 1-5, 14, 17 and 19 cannot be considered inventive for the following reasons:

Documents D1-D5 describe the *rpoB* gene sequence of various bacteria of the *Streptococcus* genus. Those sequences show very high identity with the nucleotide sequences of SEQ ID No. 1-35 in the present application. In view of D1, a person skilled in the art would be able to arrive automatically at the subject matter of claims 1-5 by putting into practice his basic knowledge and routine hybridisation and/or PCR techniques. For example, hybridisation techniques based on the use of coding sequences of *rpoB* genes do not require the generation of any particular primer. Claims 1-5 are therefore not inventive (PCT Article 33(3)).

D6-D8 describe the *rpoB* gene sequence of

Streptococcus pneumoniae (D6 and D7) and *Streptococcus agalactiae* (D8). Those sequences show very high identity with the nucleotide sequences of SEQ ID No. 1-35. D6-D8 also mention the use of these sequences in methods for detecting bacteria of the *Streptococcus* genus, as well as kits required to carry out said diagnosis (D6: abstract, SEQ ID No. 46 and 111, column 23, line 53 - column 24, line 53; D7: abstract, SEQ ID No. 4984 and 4085, pages 4, 5, 33 and 34). In view of D6, D7 or D8, all of which describe the *rpoB* genes of bacteria of the *Streptococcus* genus showing very high identity with the claimed *rpoB* genes and gene fragments, a person skilled in the art would automatically arrive at the subject matter of claims 1-5, 14, 17 and 19 by putting into practice his basic knowledge and routine hybridisation and/or PCR techniques. These claims are therefore not inventive (PCT Article 33(3)).

7. The description of the present application does not mention sequences showing less than 98.7% homology. The subject matter of claims 1-3 and 14 is thus not entirely supported by the description (PCT Article 6).

8. The prior art does not describe or suggest the consensus sequences of SEQ ID No. 6 and 7. Consequently, claims 6-13, 15, 16 and 18 appear to be novel and inventive (PCT Article 33(2) and 33(3)).

9. In the PCT Contracting States, there are no uniform criteria for assessing the industrial applicability of claim 14 in its present form. Patentability can

also depend on the wording of the claims. The EPO, for example, does not recognise the industrial applicability of claims to the use of a compound in a medical treatment; it does, however, allow claims to the first use of a known compound in a medical treatment or to the use of such a compound in the manufacture of a drug for a new medical treatment.